DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

JUN 21 2002

Our STN: BL 103132/5022

Mary Jane Nehring
Senior Director, World Wide Regulatory Affairs
Schering Corporation
Kenilworth, NJ 07033

Dear Ms. Nehring:

Your request to supplement your biologics license application for Interferon alfa-2b to revise the Overdosage section of the package insert has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Patricia Keegan for Dr. Weiss

Karen Weiss, M.D.
Director
Division of Clinical Trial Design
and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research